is significant, because a total of one-fourth of all the mammo facilities in California have gone out of business in the period of time that MQSA has been in effect, so we have got literally thousands and thousands of women whose mammograms are basically in limbo.

I saw Dr. Finder sort of raising his eyebrow there about the one-fourth. We started out with 1,200 facilities. We are now down to 800 facilities that offer mammography.

MS. BUTLER: Penny Butler from American College of Radiology. There have been some success stories. We have received a number of phone calls from consumers notifying us that their facilities have closed and the ACR staff has worked with tracking down various individuals at the facility, sometimes even going through the physicists to find out what may have happened, to find some contacts and things like that, and we have been able to help out some of the consumers, patients, retrieving their old films.

Obviously, there are some situations where we reach a dead end and we have been working very closely with FDA and trying to take some additional measures to help those individuals out.

In addition, I will be talking about this a little bit later this afternoon, but when have been notified about facilities closing, and we follow up with a closure letter, we are also asking for a contact person that we maintain in our database, so that if consumers call us, we can refer consumers to this individual to try to get their old films. It is not 100 percent, but there are steps that the various organizations have taken.

DR. FINDER: I wanted to add to what Mr. Bailey said about the bankruptcy in California. We are aware of that situation. We have been dealing with the bankruptcy court, and while it is true that at the present time, those films are sitting in a warehouse uncataloged, we have got the process started or an agreement that all those films will be cataloged and they will be made available to the patients, so we have worked to deal with these situations, so it is not totally bleak. Obviously, it is a tough situation, but when we are aware of these things, we try and deal with them to ensure that the patients maintain access.

MS. HARVEY: I think that one of the problems, we have had this problem in New York

also, is how long it takes--

DR. FINDER: Excuse me, sorry to interrupt. I just want to add one thing. Those were radiology facilities. Mammography was just a part of it. So, we have actually been able to do more for the mammography patients than a lot of the other records that are being held by those places where nobody is pushing to keep those, so I just want to make that clear.

MS. HARVEY: One of the problems with this is how long it takes and people are looking for their films. They are not looking for them in six months or two months, when you finish, they really want them now, because they have a problem and they are facing a biopsy without a comparative film or whatever.

I certainly know that it is medical misconduct in our State not to maintain your records and to have them available. I don't know whether or not any of the other States can look at this, for the doctors that continue to practice in some other realm in there.

Yes, Dr. Pisano.

DR. PISANO: I just want to comment on that, the medical misconduct issue. I really feel

that many of these facilities that close down are not necessarily administered by the radiologists, so that is the physician in the loop. So, raising whether they are guilty of medical misconduct, I think that it is probably not the case that the radiologists did anything wrong in the facility's closure.

It probably had to do with financial mismanagement and other issues, and it is almost certainly the case that the radiologists, if he or she were directly involved, would make sure the patients got the images, but the problem is they don't have control over it, and they certainly don't have the financial wherewithal to take care of it themselves.

I mean it is an administrative or business issue, so I don't really think it would be appropriate to punish the radiologists if this were to happen, at least that is the way I feel about it.

DR. FINDER: I would second that in the sense that the problems that the problems that we really had with facilities in these kind of situations are where the radiologists are not the owners and where you have got business type people,

and this is a business decision for them, and it is easier for them to go into bankruptcy and deal with it that way.

We have had situations where we are talking with the owners and also the radiologists, and the radiologists or the physicians are involved, they are all trying to make sure that the films are available, but they have no say in a lot of these matters at this point, and once it goes into bankruptcy court, nobody has any say except the bankruptcy court, so it is not a very simple situation.

MS. HARVEY: Dr. Barr.

DR. BARR: We have heard some really good stuff from the State folks here, Ms. Harvey, Mr. Camburn, and Mr. Bailey, and I think that this might even be best attacked from a state level. We are going to do all we can under MQSA to help patients get their mammogram films, but I would encourage the States who are here or anyone who can proactively talk to their States, lobby their States.

I think the State is going to be a big piece here of solving this puzzle.

MS. HARVEY: We might have to look at like

our State business laws.

DR. FINDER: Again, I would add that while we are talking about mammography films, that is a small portion of what happens when one of these places go out of business, and we can do what we can for that, but I do think that it is probably going to be up to the States to guarantee, or as best they can, the availability of all the other medical records that are involved.

The facilities around California, it turns out were not just radiology facilities, they were path laboratories, some pathology reports are involved, and I hate to even say how many documents and how many records they are talking about, but it is a huge number, much more than just mammography patients.

MS. HARVEY: Any more comments? All right.

I think there is one last question. What criteria will FDA use to determine that facilities meet the MQSA requirements for infection control?

Essentially, there has been just an addition of a line on one page. In those cases where there has not been an episode of contamination since the last inspection, the

facility should make that clear to the inspector.

Thank you. This will complete our morning session. I will be hammering that gavel again at 1 o'clock.

[Whereupon, at 11:45 a.m., the proceedings were recessed, to be resumed at 1:00 p.m.]

AFTERNOON PROCEEDINGS

[1:05 p.m.]

MS. HARVEY: Good afternoon. We are ready to start the afternoon session. Welcome back.

Our first speaker this afternoon is Nancy Wynne. She is going to talk to us about how satisfied the facilities are with our program.

Facility Satisfaction Survey

Nancy Wynne

MS. WYNNE: I am Nancy Wynne, Chief of the Outreach and Compliance Branch. Today, I am going to give you a brief overview of the Facility Satisfaction Survey that we have recently just closed out the response dates on.

A little bit of background first, though. Many of you may know that in 1996, this committee recommended that DMQR administer a survey of mammography facilities to obtain facility opinions about the current inspection process.

The objective was to gather information about the existing MQSA inspection process as it was perceived by the facilities, identify problems or areas for improvement in the process.

The first Facility Satisfaction Survey was conducted in the spring of 1997. It was a

randomized sampling of about 1,000 facilities out of approximately 10,000. There was a 65 percent response rate, which according to the Office of Management and Budget is a very good response rate.

Summary findings of the survey were published in the summer of 1998. In that survey, there were high levels of satisfaction with the overall inspection process.

Last fall, we decided to conduct a follow-up survey to see how we were doing with the inspection process under the Final Regulations. Using a computer-generated, randomized sampling, we surveyed 10 percent of existing facilities, once again about 1,000 facilities.

We used a contractor to conduct the survey, and we maintained strict anonymity of the facilities' identity. We had a very successful response rate. This response rate this year was 74 percent. Most of the information came from the radiologic technologists. Also, there was a fairly representative spread or sample of the FDA regions. The Central Region had the highest response representation, about 37.6 percent.

The findings. Well, we only have preliminary analysis at this point, but there were

generally high levels of satisfaction with the overall inspection process. For example, regarding the usefulness of publications and other resources, first, the Internet, our mammography web site.

Even though 53 percent of the respondents are aware that MQSA information and guidance is published only on the web site, we found that of those 60 percent of the respondents that stated they did have access to the Internet at work, only 39 percent actually accessed our web site from work.

Of the 80 percent of the respondents that stated they have access to the Internet at home, only 37 percent have actually accessed our web site from home.

When asked if they had used the policy guidance help system on FDA's mammography web site, approximately 78 percent responded no. However, of the 22 percent who did access and use the policy guidance help system on the web site, a resounding 93 percent found it to be very useful.

Now, directly referable materials. By this, I mean hardcopies of documents, such as mammography matters, previous inspection handouts, and other documents. This type of information

appears to be the most useful or perhaps the most available, consequently, the most used.

Preparing for MQSA inspections was one of the most referred to publications. There were 84 percent of the respondents that found it to be very useful. This preliminary information on the Internet web site versus hardcopy material indicates that we should focus on how to encourage facilities to use our web site to sign up for notification of information by way of our listserv.

Now, regarding the actual inspection process, we found that after notification, the average time spent preparing for an inspection was about 10 hours, however, only 10 percent of the respondents responded that they felt this was excessive.

Over half of the facilities indicated that they had to reschedule appointments because of the inspection, but they also stated that they had adequate time to do so. The average number of mammograms performed on a day when there was no inspection was 21. On a day of inspection, the average number of mammograms performed was 12. The average number of hours to complete an inspection was six hours.

When asked if the inspection was completed within the expected time frame, 95 percent of the facilities responded yes, and they were pleased with the time frame. When asked to rate the inspection process for the most recent inspection, 95 percent responded in the fair to excellent categories, with 65 percent of those in the excellent area.

Finally, when asked to compare the most recent inspection to the previous inspection, 30 percent responded that the most recent inspection was a better inspection. Even though the response period for this survey is over, we continue to get responses. While we can't factor these responses into the report, it is interesting to note that the latter responses are consistent with the positive responses that we received earlier on.

Next steps. We have collected a great deal of information and over the next few months we are going to be working with our contractor and statisticians to analyze the information and determine its best use.

The in-depth analysis, as well as the overall results of the survey, will allow DMQR to target inspection process improvement, and to

varying degrees it is going to be in different areas of the inspection process.

We will, of course be comparing this survey results with the previous survey results. We expect to have the final summary report on our web site after the first of the year.

MS. HARVEY: Thank you. Any questions comments?

Thank you.

Our next item on the agenda has to do with mammography access issues, an area we are all concerned about. Dr. Barr and Ms. Butler.

Mammography Access Issues

Helen Barr, M.D.

DR. BARR: On behalf of the Division, I would like to extend my gratitude to you all for being here today. I myself serve on an Advisory Committee, and know what a chunk of time it is both in the preparation and the actual attendance of the meeting. John McCrohan, who is on travel and couldn't be here, and I certainly appreciate the dedication that you have to this process.

I am only going to briefly introduce the topic of mammography access because to date we do not have a lot of hard and fast data or numbers for

you, although I will tell you some things we are working on.

We have all heard anecdotal reports of long wait times for women to be able to schedule screening mammography.

We have seen the headlines, for example, "Need a mammogram? It could take a while. Delays reach crisis levels as women wait up to five months for a screening mammogram." That was Time magazine in March of this year.

"Experts foresee crisis in access to breast tests." That was The New York Times in November of last year.

"As more women seek mammograms, many have to wait months, low payments from insurers, influx of patients put breast clinics in a bind." That was The Wall Street Journal in the fall of last year.

The House of Representatives and Senate have also heard these anecdotal reports, seen the headlines, and they have asked the Government Accounting Office to look into the issue of mammography access, and they are busily doing it at the time, and we, along with I am sure many others, are supplying them with information to use to look

at that issue.

We, in the Division, have also contracted with a group to look at the question of mammography access. Specifically, although they are going to look at more than this aspect specifically, we asked them to look at the question of even if the numbers were to remain steady-state, is that enough access in the aggregate to serve the current population needs and the fact that women at a younger age are seeking mammography screening, so they are going to be looking at that for us.

It is interesting to note, I noted when Ms. Wynne was up here, that she presented that the average number of mammograms in the respondents to our Facility Satisfaction Survey said that they did on an average 21 mammograms a day. On the last survey, that number was about 16 1/2.

Some very preliminary data coming in from our contractors suggests that mammography facilities, although maybe there is not as many of them, have expanded their capacity to serve patients over the years.

An analysis of our own database where we keep track of the mammography facilities in the United States shows that from 1996 to the present

time, there has been about a 2 percent decline in the number of fully certified mammography facilities across the country, which in and of itself doesn't seem like a large number, but issues like where the declines have been, for example, we heard Mr. Bailey express some things about California and the additional question of even if we were to remain at that 2 percent less facilities, is that enough for access.

Presently, we have about 9,548 facilities. That was as of a few days ago. The number actually changes a little bit every day.

We have been working closely with the ACR, and in April of last year, they added some additions to their closure memo, which Penny Butler mentioned when she was up here before, and they have begun to collect information about why facilities are closing.

Again, we hear anecdotal reports anywhere from insurance reimbursement is too low and financially, facilities can't stay open, to they can't find mammography technologists to do the exams, and all sorts of things. So, the ACR has begun to start to collect that information from the facilities who notify us and then that they are

closed.

So, I will let Penny take it from here and tell you about what they are doing, and then I will be available for questions when she finishes.

Thank you.

Priscilla Butler, M.S.

MS. BUTLER: Hi. Penny Butler from ACR.

[Slide.]

As of August of this year, we accredit over 12,000 units at over 8,000 facilities just to put you into perspective. Some of the numbers I am going to be presenting in a minute.

[Slide.]

I want to go through the process about how we learn of facility closures and our approach to closing them out in the accreditation system and thereby transmitting this information to FDA. Every time a facility successfully accredits with us, whether it is initial or renewal, we instruct the facility that they have certain obligations as part of their accreditation.

Among these obligations is to notify us when they close. From the facility's perspective, it is usually the last thing on their mind when they are trying to go through all of their business

dealings that they have to as they come to a decision to close, and that is to notify us that they have to close.

So, unfortunately, we don't always hear about closures directly from the facilities. So, when do we hear about it? Well, when we put the facility through a renewal or we have to communicate with them for any other reason. Occasionally, we will get an unopened renewal package.

At that point, we look into it and try to find out of the facility has closed. The State inspectors who get out there every year, if they can't find the facility anymore, the address where they think they are, they will notify the FDA or sometimes they will notify us directly that they have information that the facility has closed, and sometimes we have been notified from consumers who are contacting us to try to retrieve their old films.

[Slide.]

Our closure procedures. We have go to be very careful how we close out facilities in our system, and that is because we have had some accidents which can be very traumatic for

facilities if we do this prematurely.

We will only close a facility once we receive a letter or a closure form that is signed by either the facility's president or CEO or the facility's lead interpreting physician.

We will also close out the facility after 10 business days of us sending them a closure memo if we haven't received a response. So, for example, in the previous situations where a State or the FDA may notify us that a facility has closed, and we send them a letter, we give them 10 days, and if we don't hear back from them, then, we close them out in our system and we transmit to FDA.

By the way, on this letter, the form that we send them, we do ask them to call us immediately if we have incorrect information about this. This is necessary, this process is necessary to prevent inaccurate closures. For example, we have had phone calls from techs or receptionists or lower level administrators and departments before, whose facilities are going through ownership change, and they have called us to tell us that their facilities have closed, when, in actuality, the facility didn't close, they are just going through

an ownership change. So, we need to get verification of closure from somebody who has authority within that facility.

Sometimes facilities will relocated and they won't tell the State or other bodies, such as us, that they have moved to a different address, and when we follow up with them, we have found that they have just moved to a different address.

As Helen was saying, in April of 2001, we started manually tracking reasons for some of these closures because working with FDA, and also from the information we have been getting from facilities, we felt we were noticing an increase in closures, so we have reasons for the closures through this closure memo that I was talking about, and in addition to that, as I mentioned earlier, we are also asking these facilities for a contact person, so if we get a phone call from patients asking about retrieving old films, we can help them out and put them in touch with the right person.

[Slide.]

The analysis that I am showing you now basically goes back to April of this year, and we wanted to look at two things. One of them was confirmed facility closures, not just facilities

that expired or facilities that were not currently certified because they were waiting to reinstate as they took corrective action, but those facilities who actually either notified us that they were closed or we formally closed them out in our system.

In comparison, we also wanted to look at those new facilities that were coming on line, because we are notified by new facilities all the time that they are starting up a mammography operation.

One thing that is very clear, even though you see a lot of blips here with regards to the data, is that the new facilities opening up do not compensate at all for the facilities that are closing.

Now, the number of facilities that we see here on that month-to-month chart, there is a lot of fluctuation going on, on here. We are talking about relatively small samples, 85 in April. Some of that may have been clean-up, 25, say, in May, and then a jump up to 65, on the order of 65 in June.

I want to point out that was only up until August 8th. We don't have the full month obviously

yet for closures.

Another caveat regarding this bar chart is that these numbers are not the date that the facility closed, because a lot of times we don't know when the facility closed. We just know when we have confirmation of closure. So, this is what you are seeing here.

[Slide.]

I think from this limited data that we have right now, the most interesting thing is to note the reasons why facilities are closing. The primary reason is a global financial type of assessment that the facility has made that they cannot make a living staying in business doing mammography, and that is 26 percent.

The number of bona-fide bankruptcies that we are aware of is 3.2 percent. 7.9 percent indicated that they felt that their equipment either would not meet the 2002 requirements, or they were having problems with their equipment now, that it wasn't working, and they couldn't get it fixed, and this irrespective of any regulation out there.

6.7 percent indicated that they are having trouble finding qualified techs and sometimes

finding qualified radiologists to do the interpretations.

2.8 percent had an ownership change, and the new owners made a business decision to close the mammography operations. I do want to point out that we don't close a facility if it's an ownership change if they are continuing to do mammography, because access and services haven't been stopped. We handle that in a different way.

Another thing which is very interesting, and I know the folks in California and other States are seeing similar types of things, is that a number of facilities are making business decisions to consolidate their mammography operations, so they will take a facility with a single unit and move it to a mammography center to try to use economy of scale, and this is occurring in a large number of facilities.

Now, what does this do to access? Certainly, the quantity or the number of patients that can be examined in the units is going to be the same, but since they are geographically consolidated, does this impact on access if that remote site was closed down because of that.

As with any other study, we have 5.2

Other, and I do want to point out that we do have a large number of Unknowns, and the reason for that is these are the facilities where we get a renewal package back that hasn't been opened, and we have no contact from the facility, so we have no information on it. So, that is why the Unknown number is so large.

[Slide.]

So, let's talk a little bit about access in this limited group that we have looked at since April, we have 252 sites closed where only 83 opened. I think what is really important is that 17 of these sites were mobile sites, and mobile facilities do provide a certain advantage to access for women in remote or underserved areas. During that period of time, only four mobile facilities opened.

The other theme from this is one we have been talking about all day, and that is patients are having difficulty accessing their old films for comparisons from these closed sites, and we have already discussed these last two bullets.

So, last slide.

[Slide.]

We are continuing to monitor, to collect

and monitor this data. We share this with FDA on a routine basis, and hopefully, over a longer period of time, we will have more relevant information to look at some trends.

MS. HARVEY: Thank you.

MR. CAMBURN: I noticed you were tracking the number of facilities that were decreasing over time. Have you also tracked the number of mammography machines over time to see if they are also decreasing or perhaps increasing in number?

MS. BUTLER: We haven't analyzed on that yet. Our general feeling is that the number of units are also decreasing, but I don't have it in this analysis.

MR. CAMBURN: We have done some of that tracking in Michigan, and in the past eight years or so, we have dropped about 15 or 20 facilities, but in terms of mammography machines, that has increased by about 75 machines in that same period of time, so more machines out there in our State at least, but fewer facilities doing mammography.

DR. BARR: Yes, Jim, from the preliminary information we are getting in, that seems to be the case, he sort of expanding capacity, maybe fewer facilities but more units. I know that GAO itself

is looking at this issue on a unit basis, so we will see what comes of it. That is interesting to know what your data shows in Michigan at this point.

DR. LEE: I was wondering if the sites that had closed, whether it was a regional phenomenon, or was it pretty spread out among your sample?

MS. BUTLER: We hope to be analyzing that. Some States seem to have a higher number of closures than other States, but because the geographic areas and the populations of the different States vary, we haven't really been able to sort through that data yet.

DR. BARR: That is also one of the issues that our contractor is looking at, too, to see if there is pockets or where exactly decreased access might be if it exists.

MS. HARVEY: Any other questions for our presenters? We are all set. Thank you.

DR. BARR: We will keep you posted on this, and probably by the next meeting we will have some information from our different sources to give you.

Mammography Access Issues

Committee Discussion

MS. HARVEY: We will have our own discussion now on any issues or aspects of this question that we would like to discuss.

DR. PISANO: I am glad that the organizations are doing kind of surveys and trying to get data on this. I know the Society of Breast Imaging has also done a survey, which I don't have the results of, but I know the membership of that organization, which is mainly radiologists and technologists, as well, as some physicists.

No one mentioned it, but there is a bill before Congress right now, the Harkin bill, which is intended to increase the number of radiologists who go into breast imaging, and I think it is a step in the right direction myself, but I think that it is unrealistic to think it is going to have an impact very soon.

My limited understanding of the bill is that it will add money to increase Radiology residents, and maybe there are other aspects of it, as well, that I don't know, but my concern is it is going to take quite a while before we have more radiologists who actually read breast imaging cases.

We have a short right now of radiologists nationwide apparently, and no one spoke to that per se, although it was mentioned briefly. I think part of the issue is even if we get more radiologists, we may not get more breast imagers, and I think it is important for everyone to understand how long it is going to take, even if the Harkin bill is 100 percent very successful, before we really are going to have more people in the pipeline to read these mammograms.

We need to figure out a way besides the Harkin bill, we need to figure out a way to incentivize radiologists to go into breast imaging. There isn't a strong motive for people to go into this field right now, and there really is a problem of getting people in the field.

We are all competing. I have two openings in my practice right now. We have four, 3.2, a part-time person, and three full-time radiologists reading all the mammograms, and I have two openings. So, we are quite short-handed right now, and you talk to other radiologists, who are in positions like myself, and everybody is hiring right now. No one is fully staffed, and all of the private groups are also hiring.

Last year, at RSNA, I always interview at RSNA every year, there were like maybe three or four people who were looking for jobs in breast imaging of all the jobs there at the RSNA, the ACR has a job fair there.

So, from my perspective, getting people to go into breast imaging is a real problem right now. I don't know how to incentivize people, but when you talk to residents, they have lots of options besides breast imaging, and you hear things like, well, it is easier to be MR specialist, I don't have to deal with the regulations, and the pay is higher.

Those are the kind of statements made by residents, so we need to figure out a way to make it attractive to the trainees.

MS. HARVEY: So, I can expect that we will probably lose more facilities as they struggle. In New York, we did a demographics curve of all our radiologic technologists and found a precipitous drop-off, just as it is in the nation, of rad techs that are under the age of 30.

We have lost schools, we have fewer people who are being licensed, and so I think some facilities are struggling also to have an adequate

number of radiological technologists to do mammography, so it hits on both sides I think for staffing.

DR. PISANO: Absolutely. We are missing technologists in our practice, as well.

MS. HARVEY: There is also a bill, it's a HCFA bill to raise reimbursements under Medicare.

DR. PISANO: I believe that is correct.

MS. HARVEY: It is a proposed regulation?

MR. SHOWALTER: I am Charlie Showalter, Senior Director for Government Relations for the ACR, and I can tell you a little bit about the Harkin bill and what it contains.

Its fundamental intent initially was to try to get reimbursement to remain in statute and to set at a certain level. It has been in statute ever since screening mammography was approved for reimbursement back in 1990.

Last year, it got a bill passed, a budget bill that will remove it at the end of this year if nothing happens. We are trying to have something happen.

The Harkin bill is in the Senate, the King-Weiner bill is a parallel bill in the House, and negotiations are ongoing to see whether

anything will pass or not, but what it contains is the reimbursement construct which would put the reimbursement back into the statute for another year, and set it. Right now the bill reads at $90 as opposed to the current $69 and change.

The second aspect of the bill is the increased funding for residencies, and right now the bill reads three additional residents in Radiology per residency program.

We are hearing that that is somewhat unrealistic for some programs because of faculty limitations and the general shortage of radiologists makes it difficult to add three faculty members, so that you can have a one-to-one ratio with your residents.

We are trying to get some negotiation flexibility in there. You know, if some residency programs can absorb five and others absorb one, why, they can sort of trade around, or we could spread this out over a longer period of time, and we don't know where that is going to go, but that is what we are working on.

In addition to that, it contains funding for technologist training programs. I think that basically, the shortage of technologists, for one

reason, is a problem of the good stock market over the last few years, and there have been a lot of opportunities.

Technologists, you know, they don't make a ton of money and some of the work is not a whole lot of fun, and they have had other things they could do, and they are doing them.

So, the radiologist shortage and the technologist shortage, the best thing that has happened over the last year is the fall of the stock market, so many radiologists are not going to be in a position to retire, and RTs may be attracted back to the field.

In any case, that is a short summary of the Harkin bill and what is going on in the Congress.

MS. HARVEY: Thank you very much.

MS. ELLINGSON: I work at the ASRT, and this is our major project of the moment, along with the Federal Minimum Standards Act, the CARE Act, the bill, excuse me, to make some kind of minimum standards across the nation. There are still a lot of States who have no licensure.

But to answer to the shortage, and mammographers, of course, are a big part of it, but

it is across the board, we have found by our surveys that people are leaving the field in such great numbers, people my age are leaving and nobody is coming in the front door, and we are all going to have to be taken care of, and there is nobody to do that.

So, we are working with high school counselors. We have a new recruitment video that is aimed at young people that will be impressed with the music and the opportunities, and so forth, of our video, but we are finding that high school counselors are telling people don't go into medicine, there is no money, it is hard work, and bad hours, and they are steering our pool of new applicants into radiologic technology programs.

So, we are working really, really hard to recruit and to maintain. We call it our Work Force Development and Workplace Enhancement, and we want a better place for them to work, so that when they do come in, they don't want to leave.

It will take time to do this because you have got to recruit them in, you have got to go through the school, and then they will choose their specialty, but hopefully, our work will pay off, but it is going to be a slump before we get that

done, but ASRT is working very hard on that at this time.

DR. IKEDA: I am from Silicon Valley, so I can tell you that in the last six or seven months, since the Nasdaq fell, the traffic problem has become better, and we have been able to recruit some people to clerical positions where we could not previously before all the dot coms kind of went into the ground.

But I am glad that we are recognizing this is a problem because as I can see from Ms. Butler's data, it looks like 26 percent closed due to financial reasons and 3.2 went bankrupt. So, as always, it ends up being a matter of money.

I was a little concerned when I heard that there was some consideration to having facilities post a bond, so that when they do go bankrupt, I mean it is kind of sending the wrong message, that they can send the film somewhere.

It is important that patients be able to access their films, but certainly this is recognition of a real problem, and it has to do with finances. It is a problem, and facilities want to operate. I have never seen anybody struggle so hard to get a mammogram on a patient

who has a problem as a mammography technologist or physicians agonize over four films, trying to find cancer.

So, with reimbursement being the way it is, and the costs of operations, it has been a difficulty to stay in business, so the access problem, I am very concerned about.

DR. DOWLAT: Could I just make a comment, too?

MS. HARVEY: Certainly.

DR. DOWLAT: In Chicago, we have crisis on the number of radiologists, breast imagers. At Rush, we have certainly had it for two years, and it was sort of swapping with the University of Chicago, and now they are in the dumps, and Rush is in a better place because the radiologists moved back.

I have one question. I just want to know whether the litigation is still the highest among the mammographers. Can someone answer that question?

DR. PISANO: I don't know about recent. I have heard data from about two years ago, and I forget which organization put it out, but it was the leading cause of malpractice suits--missed

breast cancer was the leading cause of a malpractice suit in the United States about two years ago.

DR. YOUNG: I just talked about this topic last weekend, and radiologists are the source or they are the main target, and followed by ob-gynees and general surgeons incidentally. The delay in diagnosis, of course, is the problem. Misreading the mammograms accounted for about 25 percent of the cases, and then another 22 percent were mammograms read as being negative, but truly contained a cancer, and we have discussed that today. So, this is a problem, it is a deterrent to attracting young people into the technologic aspects of mammography, as well as the physicians.

MS. HARVEY: Are scanners useful? Do scanners help for flow, to be able to do more patients?

DR. PISANO: I am not sure what you are asking.

MS. HARVEY: The R2 scanner.

DR. PISANO: Oh, the R2.

DR. YOUNG: I have had some peripheral experience, not with the one that FDA has approved, but another one very recently, and it has not made

a significant contribution to the abilities of an experienced mammographer to detect breast abnormalities.

DR. PISANO: There was a nice paper published in Radiology by Berheni, Linda Warren Berheni, earlier this year. Linda Warren Berheni published a paper, she was the first author. There were about 20 authors. I think it was in January or February in Radiology about the R2 checker, image checker, and their data was very impressive, I thought, showing an improvement in ability to find cancers with that system.

Clearly, this was a study that was sponsored by the company, so we need to wait for independent--in my opinion, we need to wait for independent other studies. The first study can always be incorrect, and other studies need to verify that, but the data she published was very impressive.

The problem with those systems, and it just goes back to the cost, the cost, I can't afford it at the University of North Carolina. We are a public institution. It's a $150,000 piece of equipment, and you have to pay for someone to run it. Even with increased reimbursement, you have to

do an awful lot. Now, there is increased reimbursement if you use this system.

It is still quite expensive, and I would have to do an awful lot of them to pay for it, and I think I would lose money on it, to be honest. We are, at the University of North Carolina, breaking even right now, so anything that increases our cost is potentially dangerous to us in terms of maintaining the facility, keeping it open.

So, that is the way we made that decision even with impressive data in the literature, I just can't afford it.

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: Several institutions tried to streamline the process and upgrade their mammographic facilities. In my experience, we tried to get our administration to upgrade our facilities. That way, we can increase the level of service and the efficiency.

Although they value the service very much as a service to the community, it is always a very difficult thing to justify financially. So, although they are willing, and they are supportive, but the kind of model that we have in mind, and that I believe is very common in several other

organizations, we have a model of efficiency and high quality of care for the patient, and that costs a little money.

Well, needless to say, the moment we bring it up for this new women's center, the way we think it should be in our community, it is not approved because it apparently, at least under somebody's assessment, does not make good financial sense.

MS. HARVEY: It doesn't provide enough value?

DR. KARELLAS: Well, I don't think anybody will dispute the value to the community and the patients, the issue is that some institutions are struggling to survive today, and if an institution is facing a $50 million deficit that will grow to $100 million deficit 10 to 12 months from now, they will tell you just do mammography as you do now and we are just not interested hearing about your plans for another year or two.

Although the institution still will continue to deliver a high quality service and we don't think much is compromised, but I believe that the waiting time is not getting shorter, the patients are not happy, and overall, radiologists are frustrated. In some cases, you cannot attract

any radiologists anymore because nobody really wants to work under this kind of an environment, and we are really going in a direction that we don't want to go into.

What I am describing to you now is the situation that I am all too familiar with in the past year or so, and I believe that although some institutions have had tremendous progress and they have established just wonderful centers, some other institutions are not able to do that.

DR. RAMOS-HERNANDEZ: We have a very serious problem trying to get resources for people who live in the small towns, for people who are young, people that have no good medical insurance, and we have seen it, I think that today we saw it more clearly about the places that are closing against those that are opening.

What I see is just more a deeper gap between people who can get services and people who cannot get, because those who are moving, are moving to bigger cities or places where we have more resources, and those places that have few resources are getting without anything.

Also, about reimbursement, it is very low, and most of the institutions that are doing

mammograms right now maybe are doing what you said, they are having women's center, and they do it as part of the charity of the hospital, part of the reimbursement goes to charity.

So, to do something, there should be done something done quickly because in one way, we are encouraging women to have mammograms, we are doing education. There are women who never think about that, and when they decide to get the mammogram, they need to wait five, three, two months, or they basically cannot get it.

So, what is our message and where are we going with this, how we are going to respond and how we are going to be sure that those women, especially latinos and African-Americans are developing breast cancer at the lower, earlier ages, and I don't want to talk even about quality because we know that women who have very large breasts need to have more than one site or more than one procedure, sometimes more than one film, and they are not getting that, because the reimbursement will not pay for two or three films, or they do not have in the facility, big films, bigger films.

MS. HARVEY: Any other points? Carolyn,

do you have any other things to add from the consumer point of view?

MS. BROWN-DAVIS: No, I think that I concur, that when we talk about there being fewer services, there is going to be a large group of women in this country who are affected, not only the rural population, as you mentioned earlier, but those underserved populations who actually live in urban areas now, but what to do?

DR. KARELLAS: I will be very brief. I totally agree about the charity part, and I believe we all should be doing, in all institutions, should be very much involved in all kinds of charity, and I believe this is a most deserving kind of charity for underserved populations.

Some hospitals perhaps can do it better than others. I will give you an example. I don't think I would have much of a chance going to a hospital administration that is losing $50 million in a year, and two days ago announced that they laid off 200 people including 70 nurses, and they will lay off 500 people in a month, and 100 physicians will be laid off in mid-September.

This is not a fiction. This is, if you read the Worcester Telegram of a couple of days

ago, that is on the front page, and they wouldn't listen to me on the charity part. Now, I think that some hospitals do a much better job that we can do, and I believe that we should not give up on the charity. If we cannot afford it today, perhaps a year or two from now, I think we can turn it around and with the help of the community and provide this charity.

By no means I want to say that this should not be done. I believe that it is perhaps possible. It takes some creative minds to do it. I know some institutions do that very well.

DR. YOUNG: Is Charlie Showalter still around? Does anyone know, is the proposed reimbursement by statute from 69 to, what was it, 90-some dollars, is that both for the technical and professional component, is that total reimbursement just technical or part professional?

DR. PISANO: It is total, isn't it?

DR. YOUNG: Does anyone know, does that pertain to Medicaid patients, as well as Medicare?

DR. PISANO: I thought it was total.

DR. YOUNG: Certainly, those that can influence thoughts along this line need to have the facts clearly in hand as they speak to it.

MR. LAWSON: Herschel Lawson, CDC. I believe that it relates primarily to Medicare. Medicaid are usually handled differently, but the rates may be comparable, but I think that they are managed just differently.

DR. FINDER: I just want to kind of put this into a little bit of perspective and then ask a question, which may have a very short answer.

A lot of the things that were mentioned here, not only apply to mammography, but to radiology and medicine in general. I don't believe that the hospital is losing $50 million just because of mammography.

The other issues that are brought up are not only radiologist, technologists - nurses, we have a problem in this area in terms of nurses, so it is not all radiology, it is not mammography alone.

My question that I am going to raise to you is do you have any suggestions to FDA in terms of the MQSA program, are there any things that you think we could do as part of our program, not as lobbyists for something else, but within our program that might help here?

[No response.

DR. FINDER: And I thought that would be the answer.

DR. PISANO: I would like to comment briefly. Obviously, being of this panel, there is a level of support for this legislation and this process. I want to start out with that, and then say but, I also wear the hat of having to get my facility accredited by the ACR and inspected annually, and the process, despite that fact that only 10 percent said that 10 hours was not too long, it is relatively onerous, and it is not something that people relish or enjoy doing.

So, I am not saying that it has to be something we enjoy doing, but perhaps there is a way that we could make it less burdensome, and I don't know if the regulations were ever looked at with that in mind, in the way you have created the program or imposed the program, or whatever word is appropriate.

I don't know if anyone has really look at each step, and I am sure every step along the way, people said, yes, that was a good regulation, that was a good regulation, that was a good regulation. It is just, you know, it's the straw that broke the camel's back kind of thing.

It is nice to know that every regulation is really urgently or very important for patient care and quality, and perhaps there are some things that could be pared back and perhaps reined in a little, because it really is a pretty enormous undertaking to follow all these rules.

So, if there is any way that we could go through them--and I am not volunteering personally to go through every line by line--but if there is any way to perhaps relook at the regulations to see if there are things that could be reduced. That would be my only suggestion to the FDA.

DR. LEE: One of the tenets they tell us, of course, in public health, is do your needs assessment, so I think the survey that you are doing right now is a really good start, you know, where are the areas in the country that women aren't getting access. I think, for example, in our area, just looking at some of our records, and the women are able to get mammograms in a few weeks, so I don't think it's a problem where I am, but certainly in other areas, such as rural areas or areas in which there are large parts of the population which are underserved, they would merit more looking at.

I think the survey that you are doing is a good start.

DR. IKEDA: I would ask FDA to carefully consider any addition of new regulations and be careful about added fees. I realize that MQSA has gone a long way to improve the quality of mammography, and it has really helped patient care and helped women across the United States.

At the same time, to add a new regulation that must be inspected, look at those carefully and see if they add to the quality. What I am concerned about is the burdensome aspect. I employ a full-time quality assurance person to follow my patients, do my letters, check up on the biopsies, make sure that the right letter goes to the right patient, make sure that we follow up on the patients, and I am in a relatively large facility, and we have problems getting technologists, and I need another mammographic unit, as I think everybody does.

But it is a concern of mine to add the straw that breaks the camel's back, that will decrease access to women even more, especially in the smaller facilities, may not be able to afford as much of the regulatory process as much as like a

big facility like mine. So, that is what I am concerned about.

I think that the demonstration project of perhaps inspecting every other year that FDA has proposed, I think is a step in the right direction, if it's good.

DR. PISANO: The only other comment that I have direct to government in general, and I don't know if this is within FDA's purview or not, I think there is room for perhaps more automation in the QC process, and I think with digital we are heading in that direction, but even for film-screen systems, perhaps there is a way to make it less person-intensive.

This is really not, I don't think, within the FDA's purview except to be open to new ways to test things, but it seems that there is room for research in this area, and how we could automate some of these things, so it is not so intensive right now.

I do the same thing Debbie did when she just said about having a full-time QA person for the biopsies and things, but we lose a tech for a whole morning a week just to do the processor and QC stuff, so that is half a day a week for one

person, so that is quite a bit of time, and if there is a way to make it easier, that would be good.

I don't think there is anything currently around that could do that.

MS. HARVEY: I would like to see the inspections take a shorter period of time. I would like to see if we could work out ways to consolidate some of the information about personnel, so that if a facility has, for example, five sites, that we could have a centralized location where the information about the doctors that read, and the physicists that serve, could be found to cut down the period of time it takes doing an inspection, which is time out of a person's full day, and also is an expense of the inspector to look over that kind of data.

I would even, if I could have a wish list, might have a centralized computer that would keep information on doctors or on technologists or on physicists, and I am thinking about doing that at least for New York on physicists, just a smaller group and one that we have a more limited number on, so that that information is currently updated, and the individuals don't have to send their

documents to every one of the facilities in which they may read or work at or provide surveys for.

So, I thin, that is an area in which we might be able to shorten up the period of time to do some work.

DR. PISANO: I thought of another thing that takes more time than maybe it should have to, and that is each facility, each facility number, even if it's run by the same radiologist, had to keep separate data for each facility, so it would be nice if you could do it--

MS. HARVEY: Pool the doctors' data for medical audits?

DR. PISANO: Exactly, because knowing where--you know, I run only two facilities right now, but just it's a huge burden to have to figure out which facility that patient started from to me and separate their data out.

So, if I could do it per radiologist across several facilities, that would save a huge amount of time. That is just one thing.

MS. BROWN-DAVIS: I am looking at a process or hearing the end of a process and the beginning of a new one perhaps, because I can think that I have sat here for, I don't know, two and a

half, three years, hearing various committee members representing professional organizations to which all of you belong, and they were to have brought as, you know, one does in that type of situation, the best experience from those organizations and people who belong to those organizations, and it sounds as if the people that are sitting around the table now are saying that some of that time spent coming up with the regs might have been used differently, I guess that is the best way to say that.

And yet I wonder if this is just a process. The regs have been around now four, five, or six years, and so we have actually seen how they actually work, so I suppose that one shouldn't be undaunted by that, because there is nothing new actually, and maybe this is just a part of the process.

MS. HARVEY: I think it is an evolutionary process where you look at where you might get the best bang for your buck.

MS. BROWN-DAVIS: Because I assure you in my opinion, the FDA did not come up with these regs by themselves, you know, they took the advice of those people that were invited to be on the board,

wanted to be on the board, bringing their various expertise. That's it.

DR. IKEDA: Ms. Brown-Davis' point is a good one. As I said, the regulations, as implemented, I remember trying to implement them at my own facility, and seeing a great improvement of the mammograms that were brought in as second opinions, and so the MQSA regulations had a great impact on the improvement of the quality mammography and in diagnosing breast cancer.

So, I think that they were wonderful to start out with, I think that the regulations did a lot to improve mammography. I think we are at a place where we have to maintain that improvement and the quality, and I think we, as a committee, also recognize that the world has changed since the beginning in 1992, when the law first was passed.

Now, mammograms, I think are more regulated. People have an expectation of better quality. People are more informed. We want to keep that quality, but the economic things have changed, the eighties are gone for over 10 years, meaning that there was a great boom in doing well and then with the Nasdaq doing well, many people did well and people could spend a lot more money,

but now the economic climate has changed, and I think that we have to recognize that.

So I agree with you that the regulations did a lot for improving things. I just want us to be careful while still improving, continuing to improve mammography quality and being sure that women get treated correctly and diagnosed correctly.

MS. HARVEY: Any final words? Is there anything that the committee feels that they can do? Any letters we can write, any banners we can put up?

[No response.]

MS. HARVEY: All right. Thank you.

I think we are still running a little bit ahead of schedule, so we will start with Inspection Demonstration Project Update, and we will invite Dr. Barr back again.

DR. BARR: Thank you for all those very good comments. I only heard one good thing so far out of the whole discussion, and that is that it seems like Charlie Finder and I, if they don't treat us right here, have our pick of jobs.

[Laughter.]

DR. BARR: I just wanted to invite Charlie

Showalter up. There were some questions that came up while he was out of the room, and maybe he could address those now before I start.

DR. YOUNG: Pardon me. I had a couple of questions about the proposed legislation with the mammography reimbursement to statute for another year, that current rate is $63 going up to, what, 90 or 99, and is that just technical or is that technical and professional? The second part of the question was does this pertain to Medicaid patients as well as Medicare?

MR. SHOWALTER: It's a combination. Currently, the $69 is allocated, I believe, 68 percent technical and 32 percent physician fee, and that is a determination that was made by HCFA after the statutory amount was set.

It would apply to the same set of patients that it applies to now, and I am not certain about Medicaid. It certainly applies to Medicare. We would expect the same ratio to the 68-32 to be allocated by HCFA if the $90 gets passed, and it would not change, you may know better than I whether the current statutory amount applies to both Medicare and Medicaid, because I am not certain.

DR. YOUNG: I think that is a state-to-state determination because the States have to participate at a certain level, and that varies all over the place.

MR. SHOWALTER: That was my impression. It is my impression that in 1999, there were 4.6 million women who were examined and paid for by Medicare, and that is the population that we know we are working with. The Medicaid, as I was under the impression, was a state-by-state, and is not directly affected by the physician fee schedule, and that is what this is in lieu of is the physician fee schedule that is set for Medicare.

DR. YOUNG: Right, and I think everyone appreciates even the $90 rate doesn't reimburse the facility completely. I used to do cost accounting when I was in private practice with direct and indirect costs. It costs $130 or $140 to put a patient through for a screening mammogram.

MR. SHOWALTER: Well, we just finished a survey actually, a cost survey, and we divided it up by hospitals and private offices. Now, there are other things going on around this proposal or this legislative proposal. Anyway, the cost survey indicated that it costs about $86 in private

offices to do a mammogram, and about $125 in hospitals. Now, that was from the sampling of 37 facilities, and that is not a complete sample by any stretch, and I am sure it is more expensive in some places and less in others.

HCFA has proposed in anticipation, in current law, it goes out of statute into the physician fee schedule the 1st of the January, they have proposed an amount of 88.50 for reimbursement under the physician fee schedule, which would apply to private offices.

So, these two things have happened since we had the legislative proposal put together, and now we are beginning to wonder does it make sense to divide this up into two sets, one for private offices and another, higher number, for hospitals. We are having discussions with staffers on that at this point. We don't know for sure where that is going.

If course, hospitals are paid under a different--our hospitals are reimbursed for outpatients under a different, this APC system. HCFA will make a proposal on Friday. They put on display their proposal yesterday up on their web site, and it is a very confusing situation for

screening for outpatients, because they made no proposal for screening basically, for screening mammography. Those spaces are blank. So, we don't have any idea what they intend to pay, but we have thought that diagnostic mammography was underfunded in hospitals under the APCs, at $34 and change for the technical.

They have proposed to lower that 6 percent come next year. So, if that is an indication of what you can expect for hospital outpatients, it is our opinion that this needs to be handled statutorily, or hospitals are simply going to not be able to continue to provide mammography on an outpatient basis.

DR. BARR: Thank you, Charlie.

Inspection Demonstration Project - Update

Helen Barr, M.D.

DR. BARR: I am going to give you an update on the Inspection Demonstration Program, which you have been hearing about. For some of you, this will be old hat, and for some of you, this will be new.

[Slide.]

As you already heard from Dr. Mourad this morning, the Mammography Quality Standards Act was

reauthorized October 1998, and that will take us through October of 2002, so actually, we are beginning another reauthorization process right now.

As Dr. Mourad pointed out, the MQSRA gave us a number of different tools, and one of the things that did is gave us the opportunity, if you will, to conduct an inspection demonstration program.

[Slide.]

What MQSRA told us is that we could look at selected facilities getting less frequent inspections, and although the overall doing the project was a "may" and not a "must" or "shall," these things that MQSRA told us to do are things that we have to do, and not that we have an option of, that the program cannot be implemented before April 1st of 2001, that facilities included must be substantially free of incidents of noncompliance, that the number of facilities provide a statistically significant sample, and that the inspection frequency that we chose reasonably assure compliance with the standards.

[Slide.]

We have two goals in putting this program

together, and one is to comply with the MQSRA and what it told us to do, and the other is to ask the question - can we reduce MQSA inspection frequency for high performance facilities and maintain an assurance of quality.

[Slide.]

To put the program together, we consulted with lots of different folks. We consulted with the States primarily through the Conference of Radiation Control Program directors, with this committee itself, with our own regional radiologic health representatives.

[Slide.]

And with other offices within our center, particularly the Office of Surveillance and Biometrics, which helped us look at the statistical end of this.

We put all these things together and came up with a program plan and a schedule for implementation.

[Slide.]

The program will include States and facilities using established criteria that we set out. It will include both study and control groups. The plan is to conduct biennial

inspections for the facilities in the study group, and to conduct annual inspections for the facilities in the control group, and compare those results.

[Slide.]

For a State to participate, these are the criteria that we set out. First of all, the State can have no State laws, regulations, or unchangeable policy which require annual inspections of mammography facilities because obviously, if the State was going in there on a yearly basis by law or regulation, and we were asking the facilities that they be skipped inspection, that would be a bias to the study with the State going in there in the year between.

We decided that the States would have to agree to participate, and that they had to inspection participating facilities at the frequency that we would designate if they were to be participants.

[Slide.]

They would have to accept modifications in their State contracts based on the number of facilities to be inspected--we contract with most, but not all of the States to conduct the

mammography facility inspections, and if facilities were skipping a year of inspection, that would cause modifications in the contract--and an agreement to notify FDA of any potential serious public health risks of which they would become aware of during the demonstration program.

[Slide.]

We solicited participation from all 50 States plus the District of Columbia, New York City, and Puerto Rico, and we received agreement to participate from 14 of the 53, the group of 53, and as you can see up there, our participants are in the States or jurisdictions of Arkansas, D.C., Florida, Mississippi, New York City, New York, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Dakota, Washington, Wisconsin, and Wyoming.

About 14 more States could have potentially participated, that is, they had no laws or regulations or unchangeable policy that would have prevented them from participating, but they elected not to participate for various reasons. Some of them we heard were financial, they didn't want the skipped income of the annual inspection, and others were philosophical reasons that they strongly felt that to maintain mammography quality,

we needed to be in there on a yearly basis.

[Slide.]

We also decided to deal with the financial concern of the States, to limit the participation to no more than 10 percent of the State's facilities, so say, for example, 20 percent of the State's facilities turned out to be eligible under the criteria, which you will see for the facilities in a minute, we would make a ceiling at 10 percent of the facilities, which really breaks down to only 5 percent skipping inspection because the other 5 percent would be in the control group which would get annual inspections.

This was an attempt to not make this project financially burdensome on any of the States. We elected to include all the eligible federal facilities who met the criteria.

[Slide.]

For the facilities to participate, the facility has to maintain full accreditation and certification throughout the program. They have to anticipate providing mammography services throughout the program, and they need to undergo at least two annual inspections under the Final Regulations.

[Slide.]

During these inspections, they can receive no citations during their two most recent inspections under the Final Regulations. They can receive no regulatory compliance action or be currently considered for such regulatory action by us.

They obviously need to be located in a participating State, and they have to be selected by us to participate.

[Slide.]

Some of the limitations of the program that we see so far are that we do have a limited number of States participating, 14 States are participating, and that is obviously a small percentage of the overall States. So, that is going to limit what we get out of the program right up front.

Since we made the participation voluntary, that took out another large chunk of folks who didn't want to participate, and there is always the chance of self-selection bias from the States that agreed voluntarily to participate.

[Slide.]

Obviously, the limited number of States

limits the number of facilities, and what we see now is that we are going to have about 300 facilities is what we are predicting based on the results that we see right now of facilities who will meet the criteria that we set forth and are in participating States and fall under that 10 percent number.

The fact that we limited the participation to decrease the financial burden also limits what we will get out of the study, and obviously, that the facilities have to be in a participating State.

[Slide.]

So, all in all, what our statisticians have told us to date is because of these restrictions, this is not going to be a statistically valid study, we think, in the sense that Congress hoped that it might be.

So, dealing with that, then, we have to see where we go from here. We have a limited participation. We have a lot of internal and external limitations that were put on the program, so what we will have is a lot of descriptive statistics, and we have to deal with those and what the power is or is not of those, and the applicability of what those results will mean to a

nationwide program, and what Congress may or may not do with any results that we come up with.

[Slide.]

Timeline. We are in the process of picking the first 50 percent of the facilities inspected because the first group of facilities that would have been inspected twice under the Final Regs, that would have happened now, and we are going to distribute the letters of notification to them.

That will also give them a six-month notice period that they are not going to be inspected, that they are going to get the opportunity to skip an inspection. It will also give the States time to see who those facilities are and how that is going to affect their staffing and budgets, et cetera.

In May 2002, the first facilities will start skipping inspection, and we will begin to pick the second group. That is when the other half of the facilities will finally have undergone two inspections under the Final Regs. So, we are due to start in the spring.

I would welcome any questions or comments you would have.

MS. BROWN-DAVIS: I just had a thought as to how much did this cost, do you have any idea, you know, the project to date?

DR. BARR: No, we have not figured out internal costs. You mean as far as staff time, et cetera, to develop the program? We haven't figured out those costs, no, I don't.

DR. PISANO: Maybe you said this, but I missed it. What exactly are you going to be measuring as outcome measures, is it just citations, or what exactly are your outcome measures?

DR. BARR: We are in the process right now of developing exactly what we are going to be measuring in the inspections. The inspection itself will be the same inspection as the one that is done annually now, and we will be, of course, looking at primarily violations - did this citation-free facility bias not being in there or in the interim, while we weren't in there, then receive citations, and if so, what some of the reasons for that might be.

If they stay clean, they stayed clean, and we don't have a lot of work to do. If they did get violations, there is a number of parameters that we

could look at, did they have a significant change in personnel, such as lead interpreting physician or QC tech, and those are the things we will be looking at, you know, did they slip only to the Level 3 violations, or did they go badly in a hand basket and go to Level 1's, and the reasons for those.

We are in the process of developing all of that.

DR. PISANO: Is that the reason, I mean is it because you expect only a small difference that you don't have enough power with 600 facilities? I mean there are 300 that are going to be the study population and 300 in the control population.

DR. BARR: No, 300 is the total population, 150 in the study group and 150 in the control, and it is not purely numbers that don't give us the statistical power, it's lack of random sampling, because we are only using the States that volunteered to participate, and a number of other things that go into statistics where we don't think we are going to get the power that we might have otherwise, say, with the Facility Satisfaction Survey, which is a purely random sampling of facilities, and hold a lot of statistical weight

with that randomness attached to it.

This also does not, of course, address the issue that you raised, which is certainly one worth looking at, and was not in the minds of Congress at least at this point to do a truncated inspection. There is probably two ways to look at the whole inspection process.

We could skip inspections or we could shorten the inspection process for everyone, and those are different things to look at.

MS. HARVEY: At this point in time with so many financial pressures on facilities, sometimes another way to do things is shorter inspections more frequently, just to be remembered, you know. Nothing like having the Health Department call up and say they are dropping by to be an incentive for people to remember to do what they would normally be doing.

DR. PISANO: And there is a lot of pressure. What used to happen is people had time at the beginning of the day to do things, and now you are talking about 21 patients coming through on a unit. When it was 16, there was a little more time there to take care of some of these things.

So, that is another alternative is more

frequent, but less intensive look at a few objects. Pick your performance indicators that you are interested in.

DR. BARR: Certainly, that is another alternative, as I said, not outlined by Congress at this point, but absolutely.

MS. HARVEY: Things changed quite quickly in some ways, didn't they.

DR. BARR: There are other alternatives, and there is lots of issues surrounding this. I mean we have States that say you have go to in there every year, we have States that say we are willing to see how this pans out, we have people who say, you know, we need all these things to be checked every year. There are people that say, some of them, we have never had a dose that has been out of limit, do we need to measure the dose every time.

Well, some people would say it has never in all these years of inspections been a problem, and some would say, yeah, but the one time it is a problem, it could be a big problem, so there is a myriad of issues to weigh in all this.

DR. FINDER: I would add that we did discuss and look into the possibility of doing

shorter inspections and how that would impact, and it turns out that much of the cost of the inspection is just getting physically the person out there.

So, we looked at how much we would save in terms of being able to reduce the cost of the inspection, and it really wasn't much, if anything, because again the major cost is shipping the person out there, so it wasn't a cost savings from that standpoint, and how much the facility would benefit from having a slightly shorter inspection versus having inspection every other year.

The idea of the less frequent inspection, but doing the same type of inspection was the way we are going, and especially since Congress has put it in the Act that way, in the reauthorization act.

DR. BARR: Although we did analyze the shorter inspection from the cost standpoint, as Charlie points out, separate from that might be an analysis of what you really need to measure and sort of what are the key elements in the inspection, which really give us indicators of a problem facility, separate from the whole cost issue.

MS. HARVEY: Thank you, Dr. Barr.

Ms. Fischer will speak to us now about Full-Field Digital Mammography Certification - Update, with Ms. Butler.

Full-Field Digital Mammography Certification - Update

Ruth Fischer

MS. FISCHER: This will be a very brief overview for you, and I will gladly yield the rest of my time to Penny Butler, even if she doesn't want to.

FDA has been extending certification to include full-field digital mammography systems under certain circumstances for the past year and a half.

First of all, the manufacturer's system must be approved by FDA. That is done in the Office of Device Evaluation. It is not where MQSA is located. We are in the Office of Health and Industry Programs, however, the two offices do collaborate on these reviews and discussing clinical testing, clinical design.

MQSA does make a significant contribution in the area of the review of the quality control tests of the manufacturer and the Quality Control Manual.

What we have presently been doing is we will extend the MQSA certificate to include a digital system if it is an accredited screen-film facility. We know that facility has gone through the rigorous standards process and that the surrounding infrastructure for the facility has been approved by one of our accreditation bodies and subsequently certified.

For the past year and a half, we have not had an accreditation body for digital, and so the units have been exempt to date, and the way we wanted to cover that more substantially was then in our review of the individual facility's applications.

The things that are in the application that need to be addressed, that are of most importance, are providing the list of personnel who began working in FFDM modality prior to April 28th, 1999, when the Final Regs became effective, and after that or projected to work in the field after that.

By working with the system, we mean the interpretation, the actual performance of the mammogram, surveying of the unit.

A key point is providing a satisfactory

FFDM equipment evaluation. This includes an evaluation of the softcopy display system if that is going to be part of regular clinical use. This must be done by a qualified medical physicist, and it must be within six months prior to the facility's application for the unit.

We require, as we must by the Final Regulations, that the facility follow the manufacturer's guidelines for quality assurance and quality control tests. That is specifically specified in the Final Regulations.

Then, six months after using these tests, we require the facility to send us the results. We also take a look at that. In addition, in the application, we look at the results of the phantom image test and a sample phantom is sent in, as well.

These materials are all reviewed and if acceptable, then, we will extend the certification to include that unit for the facility. If it is not acceptable, we work with the facility, the medical physicist, in order to go through anything that we think may be deficient, but then is fully corrected, and then we can give an approval.

There has been one area of confusion that

we have become aware of recently, and it has occurred at professional meetings, so FDA would like to clarify it. It involves all categories of personnel, the interpreting physician, the radiological technologist, the medical physicist. It is about the documentation requirements for the eight hours of initial modality training of personnel working with the FFDM systems.

Those who were working with the systems prior to April 28th, 1999, were considered the pioneers of the program, are considered to have met the eight-hour initial training requirement including that work, and such personnel may provide either an attestation on an FDA attestation form or its equivalent, or documentation of the work for review during inspections.

Personnel who began working with FFDM systems after April 28th, 1999, must provide documentation of their training for review during inspections.

We are aware that this position conflicts with our currently published guidance of January 2001, stating that attestation would only be accepted if the work with FFDM units took place before October 1, 1994, and the guidance is

presently being revised to remove this conflict.

Thank you.

Priscilla Butler, M.S.

MS. BUTLER: Penny Butler from ACR. I am going to talk to you about the development of the full-field digital mammography accreditation process.

[Slide.]

Just a little history. I will skip over the first bullet. I think Ruth went through this. I want to discuss a little bit what ACR's process is and why we didn't have an accreditation program the moment FDA gave the blessing on the GE unit.

For all of our accreditation programs, we tend to develop them after our professionals - technologists, radiologists, medical physicists, have some experience with the modality, so don't come out with unreasonable standards and standards that have not really borne the results for some time.

For that reason, we didn't have a program right from the beginning, but the problem was that under the MQSA regulations, a facility has to be accredited before it can be certified.

[Slide.]

Ruth described the interim process for allowing full-field digital units to be used clinically in the United States right now, and that has been working very well. It has allowed us to obtain some data for the pilot programs, so that we can come out with a digital module.

[Slide.]

We have a subcommittee of the Committee of Mammography Accreditation. This is the Subcommittee on Full-Field Digital Mammography, which is chaired by Martin Yaffe. In fact, Andrew Karellas is one of the members of the committee.

The purpose of this committee is to develop and test a revised accreditation testing protocols and forms, and to conduct a pilot test, and this pilot test was conducted in the spring of this year.

[Slide.]

Our goals in this pilot test were to field test new phantom and dosimeter testing protocols, and I will explain why we need different testing protocols in a minute, to field test these revised instructions and forms for the facilities, and to determine if existing ACR image reviewer protocols, which were originally designed for screen-film,

were going to be adequate.

We also need to set up a system for full-field digital mammography application internally by ACR staff, and determine what changes we need for our accreditation software. I also want to point out that all of these pilots test activities going on really followed some very early, what we call alpha-testing, sort of basic research on looking at some of the quality control and the testing protocols for digital that took place way before this.

[Slide.]

Why do we need different protocols for looking at phantom exposure and dosimetry? Well, each of the digital manufacturers have different exposure control mechanisms, which are different from screen-film.

We are finding that the instructions that we give to our facilities on how to expose a phantom and how to expose, in particular, the dosimeter that we send with the phantom, have to be unit-specific.

For example, the General Electric's exposure control system is going to be significantly impacted by the thickest or the

densest part of the breast. Currently, screen-film systems have a relatively small ion chamber, which is used to measure the transmitted radiation, so the system can determine when and how to terminate the exposure, but the General Electric systems look at a much broader area.

Particularly with the phantom and the dosimeter that is used for accreditation, you do have a lucite rim around the phantom, around the block. In addition to that, we place an additional plastic holder, which contains the thermal luminescent dosimeters on top of the phantom, and that can skew the exposure and possibly the image quality results, so they would result in higher exposures of a 4.2 cm breast.

So, what the committee worked on was a revised set of instructions, were instructing the facilities for the GE units in particular to expose a 4.2 cm tissue-equivalent, homogeneous acrylic block, so it is just a piece of lucite under AEC conditions to determine the appropriate technique that is going to be used.

Part 2 involves the exposure of the accreditation phantom with the dosimeter in place. This will be done by the facility selecting the

closest manual technique that came up after the AED exposure. So, the phantom and the dosimeter will be exposed under manual conditions.

[Slide.]

There is also other unit-to-unit differences among digital equipment that we need to be aware of, and I am just quoting part of the regs which Ruth had pointed out earlier, and I want to re-emphasize this, because this is a point of confusion among technologists and physicists in particular.

That is, "For systems with image receptor modalities other than screen-film, the quality assurance program has to be substantially the same as the quality assurance program recommended by the image receptor manufacturer except for the dose part, which stays at 300 miilirads."

With the different manufacturers that are coming out with digital units, we have to have a different set of criteria for evaluating the image quality in each of those cases. Under the regulations as they currently stand, it has to be based on what the manufacturers have come up with.

[Slide.]

Just for an example, this is a laundry

list from the General Electric QAP Manual describing the technologist tests, and many of them look exactly the same as they are in the ACR-QC manual, which primarily applies to screen-film, but there are other items which are specific to digital, such as viewing conditions for the review workstation, flat field tests, MTF measurements, AOP mode and signal-to-noise checks, and certainly laser film printer QC. A lot of the others are exactly the same, however, as the Mammo QC Manual.

I also want to point out that some of the tests there are only if applicable. For example, if you are doing dry laser film processing, obviously, you are not going to have to do the analysis of fixer retention tests, which is very specific to processor quality control.

[Slide.]

Likewise, for the medical physicist, there are some tests which are specific. They are for the digital system using the SMPTE pattern to look at image quality, display device calibration looking at brightness and contrast, again, the review workstation screen uniformity, and again, a lot of the tests that are common to screen-film are there also.

[Slide.]

Let me talk a little bit about the pilot test that we ran. At the time, although we had some stragglers coming in, we had 10 General Electric 2000D units that we received test data from. We were fortunate because at the FDA approval, that we were not only able to obtain results from academic centers that were participating in research projects, and the primary research project that we drew from was the ACR Imaging Network, which is now called DMIST, and they have been very cooperative in participating in the program.

We also were able to obtain data from private practices across the United States. Our original goal was to try to pilot test some of the other digital units that were out there, such as Fisher and Fuji and Hilogic LoRad, but part of the stumbling blocks we came across were that they were not FDA approved, so there weren't many of them out there, and many of the research sites that we were hoping to obtain data from had not yet received their newer models when we were conducting the pilot test, so they weren't really available to participate.

[Slide.]

So, what did we find from our pilot testing results? The new phantom instructions that we had presented to these facilities turned out to be relatively easy to follow. We didn't have a whole lot of phone calls regarding how to do this. I don't think we had any phone calls. It was pretty straightforward.

Our subcommittee also feels at this time that there is no need to change the image evaluation criteria relative to screen-film, and this applies to both digital clinical images and phantom images. There is a few minor tweaks for, in particular, artifacts, because there is a whole genre of artifacts that may occur as a result of digital, which you wouldn't see under screen-film, but this is a minor change.

Our volunteer facilities generally felt that the process was easy to follow, and this was primarily because it was very similar to the screen-film documents that they were used to completing, however, there were some revisions that we made to these documents into the program as a result of this pilot.

One of the things that we were noting

during review of the documents that were sent to us, that many of the physicists were not aware that they needed to comply with the manufacturer's recommendations for quality control. They were basically turning in quality control tests which were more specifically related to screen-film rather than what was included in the QAP Manual.

We are going to strengthen these instructions with our final documents when they are revised and approved.

Another thing that the committee decided as a result of this is that it is an undue burden to request from facilities quality control data on both processor QC and laser QC. They felt that facilities using laser cameras to produce hardcopy, that the quality control was important information, and they felt that we only needed to request that, we did not need to request the processor QC charts.

We will be requesting basically a checklist, so that we know that they do the QC, but we will be looking at the laser QC.

[Slide.]

The subcommittee also decided that due to the differences between the manufacturers, we have to develop separate application packages for each

manufacturer at this time. That is because of the exposure control mechanisms that are different and the required QC that may be specific depending on the manufacturer.

Consequently, we are going to have to pilot test each of these manufacturer's models as they became available through the ACRIN research trials and as FDA grants approval.

[Slide.]

So, where are we in the approval process? We are currently in the middle of it. I know probably many of you never had to deal with an approval process before, but sometimes it can take a significant amount of time in order to review the document and obtain approval.

Right now, the Committee on Mammography Accreditation, chaired by Judy Destaway, they voted on the documents in the program, and after some changes, they have approved it with some changes, I should say, and for every ACR accreditation program or module, our process is that it must be reviewed by the Council Steering Committee and then after that, and after we incorporate comments from the Council Steering Committee, it has to be approved by the Executive Committee of the Board of

Chancellors.

We hope to get the package to go to the Council Steering Committee this week, and if there are no significant revisions, we hope to have final approval by the end of September.

[Slide.]

After approval, what are we going to do? Well, ACR has requested FDA to provide us with a list of facilities with the GE full-field digital units, so that we can advise them of the appropriate process for accreditation.

This is important because we are treating these digital units when they enter the accreditation process as new units, and depending on where the facility is in the accreditation process, we are either going to require the facility go through early renewal of all their units at this time or go through what we call the mid-cycle accreditation cycle.

So, if they have less than 13 months left on their accreditation, we will ask them to complete early renewal for all the units at the facility. If there are more than 13 months left on their certificate, we will ask the facility to go through mid-cycle accreditation, and this will be

at a reduced fee. The full renewal will be at the usual accreditation fee.

I think that is my last slide.

MS. HARVEY: Any questions?

DR. PISANO: Someone mentioned before, I think Ms. Barr, that you were going to require submission of accreditation materials on printed film?

MS. BUTLER: Hardcopy?

DR. PISANO: Hardcopy.

MS. BUTLER: Yes, that is correct. Phantom images and clinical images will have to be submitted to us on hardcopy.

DR. PISANO: I just want to make a comment about that. As part of the ACRIN program, ACRIN is a multi-center clinical trial that I am PI of, which is going to compare digital to film-screen mammography diagnostic accuracy, and the name of the trial is DMIST, Digital Mammographic Imaging Screening Trial.

Anyway, as part of that trial, Margin Yaffe is also in charge of our quality assurance program for that trial, and we are pilot testing softcopy submission for that. I mean we are definitely doing everything through softcopy, so it

will be interesting to see how that works, and it will be an interesting comparison.

MS. BUTLER: In order to get this off the ground relatively rapidly, we have to have hardcopy, and we are not equipped to handle softcopy at the time. That is actually a long-term goal for the College for all of our accreditation programs to be able to do, take softcopy, but it is not going to happen in the short run.

MS. HARVEY: Any other questions? Thank you.

I think we will break. Please be back about 3 o'clock.

[Recess.]

MS. HARVEY: Our next item on the agenda is from Kaye Chesemore, FDA, who is going to talk to us about States as Certification Agencies.

States as Certification Agencies - Update

Kaye Chesemore, M.B.A.

MS. CHESEMORE: Good afternoon.

Today, I will be talking about the States as Certifiers program, and throughout the talk I will often refer to it as SAC, which is an acronym, SAC, for the States as Certifiers program.

Since many of you are new to NMQAAC, I

have been asked to provide you with a little bit of background information about the program.

In August of 1998, FDA delegated the responsibility for certification of facilities to two States. Illinois and Iowa applied to the FDA and were accepted into the SAC Demonstration Project.

One thing I want to point out, a word of caution, is not to confuse the SAC Demonstration Project with the Inspection Demonstration Project that was just discussed earlier by Dr. Barr.

The SAC Demonstration Project is beginning its third year and will continue until the SAC regulations are final, and barring any unforeseen circumstances, we are hoping that they will be published and in effect in 2002.

When the regulations are effective, we will close the period for the Demonstration Project and initiate the formal SAC program. We do anticipate a seamless transition for the two states who have been participating in the Demonstration Project thus far.

We also anticipate that several other States will apply to become SAC States at that time.

Now, what does it actually mean to be a SAC or a certifying state? The SAC program is based on subsection Q of the Mammography Quality Standards Act. That subsection permits FDA to authorize a qualified state to do the following within its boundaries: issue, renew, suspend, and revoke certificates for mammography facilities; conduct annual facility inspections, enforce the MQSA quality standards, and administer other related functions.

At the same time, FDA has made the decision to retain authority over certain inspection support services that it currently provides, such as inspector training, the provision of inspection of equipment including inspecting laptops, equipment calibration, and data systems.

These responsibilities have been retained by FDA in order to preserve a nationwide consistency in inspector training and equipment calibration, and to provide a national MQSA database that can be accessed by all accreditation bodies, as well as certification agencies.

FDA's oversight of the SAC program is mandated by MQSA, and there are four ways that FDA accomplishes this. The first is through the use of

FDA staff, who act as liaisons to each state. Now, since we only have two in the demonstration program so far, I am the liaison to both, both Iowa and Illinois.

Secondly, indicators are used to measure how the States are performing as certifying agencies. The third, site visits to the States who are used to review performance, and strengthen cooperation between the participating States and the FDA, and finally, through audits and other means, we review inspector performance as part of FDA's oversight.

Through the Demonstration Project, FDA has provided feedback to the two participating States in the form of quarterly and end-of-year summaries to the two States participating.

Now, I would just like to say just a few words about the performance indicators that we use in these reports to report back to the States.

We first evaluate the State's technical staffing and training to determine if the State is adequately staffed to carry out certification responsibilities. We evaluate this in the State's initial application, and we follow it throughout the program to make sure that training and staffing

are maintained in order to carry out the State's responsibilities.

Likewise, we review the State's information systems' capability, and their initial application, and we follow that indicator to determine if the State is continuing to transfer files between the SAC State and the FDA on a timely basis.

The third performance indicator evaluates inspection and compliance activities. This indicator records such information as the number and the percentages of facilities within the State that were inspected within the quarter. We also record inspection actions for the States' facilities.

At the end of the year, we look to see if at least 90 percent of the fully certified mammography facilities were inspected, and if any inspection findings were resolved within the four months, and if missed and deferred inspections were rescheduled.

The fourth and last indicator, which concerns the actual certification program, evaluates the percentage of certificates that were promptly issued within the required 10-day period

in a given calendar quarter.

In addition to the performance indicators and the quarterly reports that I have just discussed, our oversight of the project includes site visits, and we anticipate that site visits will occur annually.

To conclude, we are presently revising the performance evaluation instrument, and these performance indicators will be expanded or may be expanded or revised throughout the program as it grows and expands. We do look forward to other States joining the SAC program in the future.

Thank you.

MS. HARVEY: Thank you. Any questions?

MS. RIGSBY: Is this a voluntary thing for the facilities in those two States?

MS. CHESEMORE: No, it is not. They automatically are certified by either the State of Illinois or Iowa in this particular instance, and any other SAC State that would come into being.

One thing I may tell you is that with SAC States, they cannot go outside their State's boundaries. With accreditation bodies, they don't have that restriction although it hasn't occurred yet.

MR. BAILEY: Presently, not all States are using FDA laptops or necessarily FDA equipment. Under certifying, I would assume that that would continue to be an option.

DR. FINDER: If you have got very specific questions about the program, I don't think this is the forum to air it. You can just discuss it amongst yourselves and get the details.

MS. HARVEY: Other questions, comments?

Then, let's go on to the next item, which is the Future Direction of the MQSA Program.

Future Direction of the MQSA Program

MS. HARVEY: This is an opportunity for us to look forward. We have talked today about the many miles the mammography program has come, and I can certainly speak for New York for some of the early facilities 10 years ago when we would try to put one of the old Kodak phantoms in the beam, and not visualize anything, to this point in time where we have such high expectations as to what these images are going to look like, every single one of them.

But then we say to ourselves we have come this far, now, when we look forward, what do we look forward to the evolution of this program over

time.

I mentioned earlier one of the issues in particular that I am interested in, which is perhaps a reduced period of time for the inspection, but I am also interested in something that we have tried to do, is that during the course of the inspection, that the inspectors take a look at the completed clinical images, not because we are radiologists, not because we are rad techs, but because once in a while there will be a facility in which the image quality is unacceptable, and what the inspector can find by looking at those images is something that may have fallen through the cracks, which is what we have seen.

The point would be to find the very--these are some of the worse images you have ever seen as an inspector, not that you are making a split between good quality and better quality, but images that really call out to have some form of review by someone who would be in a better position than the inspector to actually look at them.

So, I think it is one of the important things for us to think about over time is how can we incorporate more of a review on the inspector's part while they are there at the facility.

I am happy to listen to your concerns or thoughts about that.

MR. CAMBURN: In our State, and I don't know how much this would be in the other States, but in our State, none of our inspectors are x-ray technologists. They are all people who have at least a Bachelor's or Master's Degree with a major in physics.

They right now would have no training or no skill whatsoever in looking at clinical films and judging whether they are good or bad. In fact, sometimes we seem to struggle over interpreting phantom films, and the way we do it, we have at least three independent MQSA inspectors look at every film we take. Then, a fourth person looks at their scores and comes up with a consensus. Sometimes we can't even agree very well among ourselves on something as objective as a phantom film.

I am not sure how successful we would be trying to evaluate a clinical film.

MS. HARVEY: What I am not suggesting is that you look at clinical films as though you were a radiologist or a radiologic technologist, but for serious problems in processing, developing, where

you find extreme artifacts, films that haven't been properly cleared, films that the optical density is either extremely high, extremely low, very gross difficulties, very, very gross.

This is not looking at images to split hairs between, well, you could have done this a little better. That is not the point of this. This is the goal. Our goal here is the best quality we can get, and while we are not going to be the judges from a radiographic, we can learn, just like you can learn art criticism. You look at a picture long enough, you will learn by doing what is the extreme, and that is what I am looking for, it is the extreme.

MR. CAMBURN: In these cases, these are films that the mammographer would have looked at, and the radiologist would have interpreted, and not rejected?

MS. HARVEY: Right. So, we are only looking at a very few facilities out of all the 10,000, but we certainly had a case in New York where the end product films were, we believed, to be below diagnostic quality.

MR. CAMBURN: Even though the radiologist thought they were okay.

MS. HARVEY: Even though it was MQSA-accredited, certified, and passed the inspections.

DR. IKEDA: I have a concern about adding another layer of inspection. We have just discussed--you know, granted we want to catch bad films or facilities that do not have good diagnostic quality or something that may have fallen through the cracks, but my concern here, as we have already talked about, trying to limit the number of items that we are going to be looking at during the inspection.

My second concern has to do with interpretation or intra-observer and inter-observer variability. I know the ACR and FDA and the States have gone through a rigorous process to do clinical image evaluation, or maybe somebody from the ACR can speak to this, but I know that they have multiple training sessions.

As a facility director, we do a very tedious and thorough job looking at our images. I am concerned, I thought that most of the poor images, I think would be caught by that particular process, and like I said before, MQSA has done a tremendous job in trying to weed out bad facilities

or, well, suboptimal facilities in this day of political correctness, but facilities that were not doing good images.

So, it was my thought that those images would probably be caught by those particular processes. My concern is to take this one step, even though it is a good thought and it is a noble aspiration, but to apply it to 10,000 facilities, that is more money, more time, more burdensome of a process.

I wonder, number one, what is going to be the training of the inspectors who is going to be the final judge, what is going to be the follow-up for it, and how many are actually out there in which this applies.

I know that there must be at least one, because it has been your experience, but I just want to raise my concern and say that I don't know, and it is something I would like to think about.

MS. HARVEY: I would trade you some of the other tests.

DR. IKEDA: That is something else we can talk about.

MS. HARVEY: Because when I started way back, my very first job when I graduated from

college was to work for a company that made photographic film, and I worked in the Motion Chemistry lab, and I spent that year during quality control. So, when I went out to start doing my first inspections, I immediately saw the films, and this was back in the seventies--I am giving away more data here than maybe I wanted to--and I was appalled. I was appalled because of the quality I saw, and this was just when the FDA was starting to print all their huge quantity of wonderful books about how to do quality control.

Well, I was there, I was ready, because I was looking at films that were--my theory was any film that is worth taking is worth taking well or don't take it. So, I think to have a whole program, such as we have, and not to have, when we have an inspector in that facility every single year, to not spend the five or 10 minutes to get a feeling for what is happening at that period of time in that facility, it is an opportunity that we are not taking.

Like I say, I will trade you over tests, because to me, that is one of the major things we want there is quality images.

DR. PISANO: I think that we actually are

getting the kind of information you are interested in already at the inspections. I think the case you cited is really quite exceptional because we are doing--I mean the inspector is already shooting a phantom, so we know how well the processor and the machines are functioning that day. The inspector is already checking a lot of other parameters that are going to reflect image quality.

So, I agree with Debra Ikeda on what she said about adding burden to both the facility and the inspector. I am actually quite concerned about the inspector's ability to do it, just as Dr. Camburn mentioned a minute ago.

I am concerned about, you know, I was a participant for many years in the ACR's film inspection program. I was radiologist reviewer for clinical images. I was impressed with how frequently my partner and I, who were both trained radiologists and who have been through the ACR's program--the way it works is they send you cases, and you review them blindly, you don't know what the other person is going to say--and how frequently we are given a report card by the ACR what percent of the time we agreed with each other, and how frequently we did not agree with each